K00 2780

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EXHIBIT #1
4 pages

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____

1. **Submitter's Identification:**

   Viatronix Inc.
   25 Loop Road
   Suite 206
   Stony Brook, NY 11790

   Contact: Mr. Jeffrey Cohen, Director of Engineering

   Date Summary Prepared:

   August, 28, 2000

2. **Name of the Device:**

   Viatronix Visualization System

3. **Predicate Device Information:**

   a. Advantage Windows 3D with Navigator Option, K#954355, General Electric Co., Milwaukee, WI (892.1000, Product Code LNH)

   b. Realtime 3D Diagnostic Workstation, K#97310, (Presently called "3D Virtuoso Workstation"), Siemens Medical Systems, Inc, Iselin, NJ (892.2050, Product Code LLZ).

   c. VoxelView ® K#953259 Vital Images, Inc. St. Paul, MN (892.2050, Product Code LLZ).

4. **Device Description:**

   The Viatronix Visualization System (VVS) contains all of the required hardware and software components to provide interactive 3D and 2D views of diagnostic CT and MR

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images. The views include both inner and outer surface 3D volume rendered images as well as orthogonal and multiplaner reformatted 2D images. This ability to view the dataset in different perspectives from which it was acquired is performed by first transferring DICOM images from the MR or CT scanners to the Viatronix Visualization System, automatically identifying regions of interest and displaying these regions to the user in the above mentioned views. The user can navigate both freely within the dataset/region of interest, or follow automatically computed paths to fly through or fly around the outside of the structure. Measurements of the viewed anatomical structure can be made.

5. **Intended Use:**

The Viatronix Visualization System is intended to receive patient specific data sets of CT or MRI images and can be used for:

- 3D presentation of complex anatomical relationships and specified structures within the complete data set;
- System generation of a 3D model of the desired anatomical structure;
- Viewing of the volume rendered and Multiplanar Reconstruction (MPR) representations of the desired anatomical structure providing additional supplemental information to support interpretation and treatment planning;
- Viewing the inner and outer surfaces of organs as well as within their walls providing additional supplemental information to support interpretation and treatment planning;
- Planning and following a navigation path through the desired anatomical structure;
- Programmed and interactive navigation and flythrough within the 3D volume including specified organs and structures;
- Measurement of position, length, angle, and volume of anatomical structures within the 3D volume.
- Common core technology with specialized interfaces for different anatomical structures.

6. **Comparison to Predicate Devices:**

The Viatronix Visualization System (VVS) utilizes the same technological characteristics as the three predicate devices, the G.E. Navigator, the Siemens 3D Virtuoso, and the Vital Images VoxelView. They all provide multi-view user interfaces with combinations of 2D and 3D views correlated together for enhanced visualization. They all provide measurement tools for analysis of the observed structures, allow adjustment to virtual lighting parameters to emphasize details, and provide window/level adjustment of the 2D Views to enhance features.

VVS and all three predicates, provide both external and endoluminal 3D views. As with VoxelView, VVS utilizes direct volume rendering for all of its 3D views, both transparent volume images and visible surface views. While 3D Virtuoso provides volume rendered images, in some cases surface extraction is run first. GE Navigator utilizes surface extraction techniques for all 3D views. In VVS and VoxelView, the

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computation to extract the surfaces occurs during rendering instead of during pre-processing. This allows changing the density value to be visualized, but creates the same surface as if the extraction has occurred before rendering. For changing the mapping to opacity during translucent views, VVS is similar to both the Siemens 3D Virtuoso and VoxelView devices.

With VVS, the user may choose between automatic path planning or interactive flight control. The GE Navigator also automatically plans a path, but requires the user to press a button for each step. In essence, the VVS system performs the Navigator "auto step and align" function multiple times until the end of the organ is found.

Siemens 3D Virtuoso performs semi-automatic segmentation by calculating each step of the segmentation process, allowing the user to view the results and then interactively adjust any incorrect features. VVS is similar, but performs the complete segmentation before requiring the user to interact with the system to adjust the results.

We conclude that the subject device, the Viatronix Visualization System (VVS), is as safe and effective as the predicate devices and poses no new questions of safety and effectiveness.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Testing was conducted using phantoms with structures of a known size and distance from the start inserted into the phantom. The person using the system did not have advance knowledge as to the number of structures nor their size or location. An independent reviewer then compared the test results with the actual phantoms and made an assessment as to accuracy.

The Viatronix Visualization System has been developed in a manner consistent with accepted standards for software development, including testing protocols. Testing on phantom objects has determined its level of accuracy, which is substantially equivalent to that of the predicate device. The product has shown itself to be reliable, easy to use and capable of rendering useful 3D medical images.

We conclude from these tests that Viatronix Visualization System is substantially equivalent to the predicate device in its ability to render 3D images for use in medical diagnostics. In comparison to optical endoscopy, the Viatronix Visualization System is able to visualize structures of similar size and shape.

Clinical studies were performed under IRB (Institutional Review Board) overview, that included Patient Consent Forms, in accordance with 21 CFR Part 52).

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8. **Discussion of Clinical Tests Performed:**

Clinical tests on patients were done to verify that the system performed as intended with a broad sampling of input data. Each patient was assessed as to whether the core functionality of the system permitted fly through and visualization. Comparison was made with optical endoscopy to give a qualitative judgement as to the ability to visualize structures. Comparison to the predicate device was also made as to quality and effectiveness.

The Clinical data was reviewed by a radiologist who determined that the rendering was accurate and medically useful. The radiologist was experienced with the predicate device and found it substantially equivalent in essential features with improvements in the speed of rendering and the ease of performing segmentation.

9. **Conclusions:**

The Viatronix Visualization System has the same intended use and similar technological characteristics as the General Electric Advantage Windows 3D with Navigator Option and Siemens Medical Systems Realtime 3D Diagnostic Workstation (3D Virtuoso) predicates. Moreover, clinical and non-clinical testing demonstrate that the Viatronix Visualization System is substantially equivalent to the predicate devices in its ability to render 3D images in providing additional supplemental information to support medical interpretation and treatment planning. In comparison to optical endoscopy, the Viatronix Visualization System is able to visualize structures of similar size and shape. The Viatronix Visualization System does not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2000

Viatronix Inc.
c/o Susan D. Goldstein-Falk
MDI Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

Re: K002780
Viatronix Visualization System (VVS)
Dated: September 1, 2000
Received: September 6, 2000
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Exhibit B

510(k) Number (if known): K002780

Device Name: Viatronix Visualization System (VVS)

Indications For Use:

The Viatronix Visualization System is intended to receive patient specific data sets of CT or MRI images and can be used for:

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- System generation of a 3D model of the desired anatomical structure;
- Viewing of the volume rendered and Multiplanar Reconstruction (MPR) representations of the desired anatomical structure providing additional supplemental information to support interpretation and treatment planning;
- Viewing the inner and outer surfaces of organs as well as within their walls providing additional supplemental information to support interpretation and treatment planning;
- Planning and following a navigation path through the desired anatomical structure;
- Programmed and interactive navigation and flythrough within the 3D volume including specified organs and structures;
- Measurement of position, length, angle, and volume of anatomical structures within the 3D volume.
- Common core technology with specialized interfaces for different anatomical structures.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **(Per 21 CFR 801.109)** **OR** **Over-The-Counter Use** ____ **(Optional Format 1-2-96)**

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002780